Docket No.: 30042-00001-US (PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Application No.: 10/735,362 Confirmation No.: 1804

Filed: December 12, 2003 Art Unit: 1611

For: METHOD AND PROCESS FOR PRODUCING
YOUTHFUL-APPEARING SMALL-PORED
AND SMOOTH SKIN

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## DECLARATION UNDER 37 CFR 1.132

l, Diana J. Parsons declare that I am the inventor of the inventions disclosed and claimed in the above identified US Patent Application and further declare that the following two case studies were carried out by me and/or under my direction and are presented herein to further demonstrate the effectiveness of the present invention.

The first patient is representative of someone in their mid to late twenties and is a female about 27 years old who does not yet manifest the skin damage caused by childhood exposure to the sun. The underlying assumption is that wrinkles are caused by sun damage to the skin's inherent elastic and fibrous tissue, which over time and the pull of gravity causes the skin to sag. The deepest wrinkles occur around the mouth and eyes because after the baby fat is lost in the face, the underlying muscles connect directly to the skin. There is no surgical treatment for these lines since the muscles reattach to the skin within a year if detached. Prior to treatment, she still had active acne, oily skin and moderately sized pores. This patient like others in this category uses branded Retin-A 0.1% cream two nights per week and undergoes the minimal laser treatments according to the present invention of six treatments during the first six months, a single booster at six months, then a single treatment every six months. The laser treatment was with a Q- switched Nd:YAG laser and included exploding carbon particles on the surface of the skin with the laser light, whereby the laser light having a pulse duration within the range of 0.001 to 1 microsecond, a wave length within the range of from about 800 nm to 1200nm, and a fluence within the range of from about 1 to 3 J/cm<sup>2</sup>. The treatment leaves the

epidermis intact and normal and produces a wound in the high dermis. The patient was treated over A eight years resulting in the eradication of acne and the production of small pored and smooth skin.

Representative of another group of patients is second patient who is a female about 47 years old. She is a natural redhead, states that she is allergic to most sunscreens, but nonetheless plays tennis for an hour every morning and six hours of golf on most Fridays. She had extensive sun damage to the face, neck and upper chest. She had the ablative CO2 laser treatment to her face five years ago at age 42; the CO, laser was too powerful to use anywhere except the face. She demonstrates the classic result of this ablative technique of differential pigmentation, shiny, atrophic unnatural appearing skin in marked contrast to the severely sun damaged neck and chest. The history of allergies to sunscreens indicates intolerance to the chemicals that inhibit UVA rays, the most damaging. After one year of the use of Retin-A 0.1% cream and the O- switched Nd:YAG treatments as outlined above for the first patient, her face skin looks more like the rest of the body because the shiny ablated look has a matte finish. This also diminishes the differential pigmentation. The face skin still looked somewhat abnormal. The sun damage to the neck has improved, but the upper chest skin looked about the same. During the second year, treatments were given every three months instead of every six months as for the first patient. After two years of the use of Retin-A 0.1% cream and O- switched Nd:YAG treatments, the creation of normal appearing facial skin (although the differential pigmentation still persists) and significant improvement to the neck skin result. However, the upper chest skin did not improve since the patient used the RetinA only on the face and neck. This patient demonstrates the synergistic effect of using Retin-A with the O-switched Nd:YAG laser.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date June 30, 240 Sangifican' Diana J. Parsons